

Message Text

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FOR JIM SHINN EDRC REVIEW

E.O. 11652: NA
TAGS: BEXP, ECEM, ETRD, JA

SUBJECT: TRADE FACILITATION COMMITTEE: PROPOSED STUDY
ON TRADE BARRIERS TO U.S. PHARMACEUTICAL FIRMS IN JAPAN

COMMERCE FOR BIEPR/OCA/JPN:GLICK AND STR FOR BARREDA

1. SUMMARY: IN LINE WITH RECENT WASHINGTON AGENCY/
PHARMACEUTICAL MANUFACTURERS ASSOCIATION (PMA)
CONVERSATIONS ON POSSIBILITY OF INITIATING SPECIAL
STUDY (UNDER AUSPICES OF TRADE STUDY GROUP) ON
PHARMACEUTICAL MARKET ACCESS PROBLEMS, EMBOFFSMET
WITH REPS OF LEADING U.S. PHARMACEUTICAL FIRMS TO
DETERMINE EXTENT OF NTB'S AND POSSIBLE REMEDY.
CONCLUSION IS THAT PROBLEMS DO EXIST IN MHW
APPROVAL PROCESS, BUT THAT THESE ARE LARGELY INSTI-
TUTIONAL AND NOT DISCRIMINATORY TRADE PRACTICES.
SOME FIRMS DISAGREE WITH THIS ASSESSMENT. HOWEVER
MAJORITY RESPONSE IS THAT SUCH NTB'S AS EXIST ARE
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MINOR AND CAN BE EFFECTIVELY DEALT WITH BY THE U.S.
FIRMS. THUS, WE DO NOT FEEL THAT A SUFFICIENT BODY
OF COMPLAINTS EXISTS AT THIS TIME TO JUSTIFY A LARGE
SCALE INDUSTRY INVESTIGATION OR TSG-TYPE EFFORT.
STILL, WE DO THINK THAT SEVERAL LIMITED ISSUES DESERVE
FURTHER INVESTIGATION AND POSSIBLE USG INVOLVEMENT
TO REMEDY.

END SUMMARY.

2. MEETINGS WERE HELD WITH SENIOR EXECUTIVES OF MSD (MERCK), DAINABBOT (ABBOTT), WARNER-LAMBERT, PFIZER-TAITO (PFIZER), AND UPJOHN PER PMA LIST. CONTACTS VIA ACCJ WERE WINTHROP, LEDERLE, AND TRANSEARCH (PHARMACEUTICAL CONSULTANTS). FOLLOW-UP CONTACTS NEXT WEEK WILL INCLUDE SMITH-KLINE-FRENCH, BEECHAM, SANDOZ, BAYER, HOECHST. THESE INCLUDE 100 PERCENT OWNED SUBSIDIARIES, JOINT-VENTURES AND AGENT OPERATIONS. EACH FIRM WAS QUERIED FOR ANY NTB'S IN CUSTOMS, REGULATORY, MARKETING, AND LEGAL AREAS.

3. THE FOLLOWING PROBLEMS WERE NOTED, IN DESCENDING ORDER OF EMPHASIS.

A. MHW AND MAF APPROVAL FOR NEW DRUG TYPES WAS UNIFORMLY DESCRIBED AS COMPLEX AND SLOW. ALL ADMITTED, HOWEVER, THAT THIS IS NOT NOTABLY DIFFERENT FROM THE FDA. THE 2 KEY PROBLEMS ARE THAT BASIC TOXICITY AND DOSAGE TESTS MUST BE REPEATED IN JAPAN, AND THAT THE ACTUAL EVALUATION PROCESS AS PERFORMED BY OUTSIDE EXPERT ADVISORY COMMITTEES IS INFORMAL AND PROVIDES NO DUE PROCESS. SHORT OF STANDARDIZING INTERNATIONAL DRUG TESTING PROCEDURES THERE IS NO EVIDENT SOLUTION TO THE FIRST PROBLEM. UNCLASSIFIED

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THE REQUIREMENTS ARE THE SAME FOR BOTH U.S. AND JAPANESE FIRMS. ONE FIRM SUGGESTED THAT MHW ISSUE CLEAR WRITTEN GUIDELINES STATING HOW U.S. BASIC TEST PROCEDURES COULD BE ALTERED TO SATISFY THE JAPANESE AUTHORITIES. MOST FIRMS SAY THEY SIMPLY DO PARALLEL TESTING IN BOTH COUNTRIES. THE TECHNICAL BARRIERS (STANDARDS) CODE UNDER NEGOTIATION IN MTN MAY POINT THE WAY TO EVENTUAL JAPANESE ACCEPTANCE OF FOREIGN TEST RESULTS. BUT GIVEN MHW'S PAROCHIAL VIEW ON INTERNATIONAL IMPLICATIONS OF ITS ACTIONS, WE SUSPECT MHW WOULD WISH TO TAKE ADVANTAGE OF CODE EXCEPTIONS, ASSUMING SOMETHING LIKE THE PRESENT DRAFT IS NEGOTIATED. THE SECOND PROBLEM IS ENDEMIC TO MOST GOVERNMENT-BUSINESS RELATIONS IN JAPAN. JAPANESE FIRMS TEND TO GET FASTER TYPE APPROVALS THAN U.S. FIRMS BECAUSE THEY ARE MORE FAMILIAR WITH MHW AND THE ADVISORY COMMITTEES. THE CONSENSUS IS THAT THERE IS LITTLE OVERT OR COVERT DISCRIMINATION IN THIS AREA; IT IS RATHER A MATTER OF PROFESSIONAL EXPERTISE. MITI IS IN PROCESS OF OPENING ONE OF ITS ADVISORY COMMITTEES TO IMPORTERS. PERHAPS WE SHOULD ATTEMPT TO PERSUADE MHW TO DO LIKEWISE.

B. THERE IS A DE FACTO CASE OF DISCRIMINATION AGAINST FOREIGN-MANUFACTURED DRUGS DUE TO MHW-ENFORCED "PRIORITY TESTING PERIOD" REGULATION WHICH GRANTS THE FIRST VENDOR OF A NON-PATENTED OR PATENT-EXPIRED DRUG A LIMITED SELLING MONOPOLY TO ESTABLISH CLEAR RESPONSIBILITY SHOULD ANY SEVERE SIDE-EFFECTS OCCUR. THIS MONOPOLY PERIOD IS 3 YEARS FROM A DRUG MADE IN JAPAN AND ONLY 1 YEAR FOR A FOREIGN-MADE DRUG. THE MHW RATIONALE IS THAT FOREIGN DRUGS HAVE USUALLY BEEN ON THE MARKET FOR SOME TIME OVERSEAS. HENCE, MOST SIDE-EFFECTS HAVE ALREADY BEEN IDENTIFIED. HOWEVER, THIS CAN HAVE SUBSTANTIAL NEGATIVE MARKETING IMPACT ON FOREIGN FIRMS IN JAPAN. FURTHER, THE DRAFTING COMMITTEE FOR THE REVISED PHARMACEUTICAL AFFAIRS LAW

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IS CONSIDERING EXTENDING THIS PERIOD FROM 3 TO 6 AND

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FROM 1 TO 2 YEARS RESPECTIVELY FOR JAPAN AND FOREIGN NEW DRUGS. THIS ISSUE DESERVES FURTHER ANALYSIS.
C. SEVERAL COMPLAINTS IN THE AREA OF PATENT AND TRADE-MARK PROTECTION WERE MENTIONED. JAPAN'S RELATIVELY RECENT SHIFT FROM A PROCESS TO A PRODUCT BASED PATENT LAW WILL SOLVE MANY OF THESE PROBLEMS AS BACKLOGS ARE

WORKED OFF. TRADEMARK ISSUES ALSO EXIST BUT THIS IS A PROBLEM NOT LIMITED TO PHARMACEUTICALS. ALL FIRMS ALSO HAD COMPLAINTS ABOUT IRRITATING AND COMPLEX CUSTOMS CLEARANCE PROCEDURES, BUT AGAIN NOTHING MAJOR IS INVOLVED. JAPANESE CUSTOMS MAY APPLY VALUATION UPLIFTS WHEN A COMPANY IMPORTS FROM A RELATED FIRM, WHICH IS OFTEN THE CASE FOR THE FIRMS INTERVIEWED.

D. ANOTHER AREA OF COMPLAINT HAS TO DO WITH GOJ REGULATION FOR NEW DRUG APPLICATION THAT ALL NON-CLINICAL TESTS MUST BE PERFORMED AND APPROVED IN JAPAN BEFORE CLINICAL SUPPLIES MAY BE IMPORTED. DEPENDING ON MHW REQUIREMENTS FOR NON-CLINICAL TESTS FOR A GIVEN PRODUCT, JAPANESE FIRMS HAVE DISTINCT TIME ADVANTAGE OF DEVELOPING SIMILAR PRODUCT DOMESTICALLY IN THAT THEY CAN CONDUCT CLINICAL TESTS UNCLASSIFIED

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CONCURRENTLY WITH NON-CLINICAL TESTS. WHILE THIS PROBLEM DOES NOT JUSTIFY A FULL TSG STUDY, PERHAPS PMA WOULD LIKE TO CONDUCT A UNILATERAL STUDY OF THIS SUBJECT FOR PRESENTATION TO GOJ THRU THE EMBASSY.

3. EMBASSY WILL FOLLOW UP ON REMAINING CONTACTS AND REPORT. IN LIGHT OF OUR FINDINGS, PMA MAY WISH TO RECONSIDER PROPOSED STATE/USDOC PRESENTATION TO PMA FOR POST ADVISORY COMMITTEE ON JULY 6. A MODEST EXPLANATION OF OUR FINDINGS PLUS DISCUSSION OF PRIORITY TESTING PERIOD ISSUE MAY BE MORE APPROPRIATE. STATE IS REQUESTED TO TRANSMIT A COPY OF THIS CABLE TO LEONARD HOLBROOK AT THE PMA IN DC AS PER PRIOR UNDERSTANDING.

MANSFIELD

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